



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region IX  
90 – 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

MAR 31 2010

Report Number: A-09-08-00034

David Maxwell-Jolly, Ph.D.  
Director  
Department of Health Care Services  
1501 Capitol Avenue, MS 0000  
Sacramento, CA 95899-7413

Dear Dr. Maxwell-Jolly:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicaid Compound Drug Expenditures in California for Fiscal Years 2004 and 2005*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Jerry McGee, Audit Manager, at (323) 261-7218, extension 603, or through email at [Jerry.McGee@oig.hhs.gov](mailto:Jerry.McGee@oig.hhs.gov). Please refer to report number A-09-08-00034 in all correspondence.

Sincerely,

Lori A. Ahlstrand  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Ms. Jackie Garner  
Consortium Administrator  
Consortium for Medicaid and Children's Health Operations  
Centers for Medicare & Medicaid Services  
233 North Michigan Avenue, Suite 600  
Chicago, IL 60601

Department of Health & Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF MEDICAID COMPOUND  
DRUG EXPENDITURES IN CALIFORNIA  
FOR FISCAL YEARS  
2004 AND 2005**



Daniel R. Levinson  
Inspector General

March 2010  
A-09-08-00034

# *Office of Inspector General*

<http://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health & Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## *Office of Evaluation and Inspections*

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

## **THIS REPORT IS AVAILABLE TO THE PUBLIC**

at <http://oig.hhs.gov>

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

## **EXECUTIVE SUMMARY**

### **BACKGROUND**

Pursuant to Title XIX of the Social Security Act, the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In California, the Department of Health Care Services (the State agency) administers the Medicaid program.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including California, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs, indicates a drug's termination date, if applicable, and specifies whether the Food and Drug Administration has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form. For each compound drug claim, CMS guidance states that the drug code and corresponding quantity for each ingredient must be included on the claim for Medicaid reimbursement.

In April 2009, we issued a report on California's Medicaid outpatient drug expenditures for Federal fiscal years (FY) 2004 and 2005 (A-09-07-00039). We excluded from our review the total of approximately \$75 million for compound drug expenditures for which the State agency did not have readily available supporting documentation that identified the individual drug ingredients. This review covers \$58.3 million of that amount, which represents compound drug claims that the State agency maintained in electronic format.

### **OBJECTIVE**

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid compound drug expenditures complied with Federal requirements related to whether the compound drug ingredients were terminated, included on the CMS quarterly drug tapes, or less than effective.

## SUMMARY OF FINDINGS

The State agency's claims for reimbursement of Medicaid compound drug expenditures for FYs 2004 and 2005 did not fully comply with Federal requirements. Of the \$58.3 million (\$29.5 million Federal share) reviewed:

- \$759,078 (\$383,467 Federal share) represented expenditures for compound drug ingredients that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tapes before the drugs were dispensed and
- \$2,649,556 (\$1,341,413 Federal share) represented expenditures for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Federal reimbursement.

The remainder of the \$58.3 million reviewed met the Federal requirements described in our objective.

The State agency had inadequate controls to ensure that all of its compound drug expenditures complied with Federal requirements related to whether the drug ingredients were terminated and included on the quarterly drug tapes.

## RECOMMENDATIONS

We recommend that the State agency:

- refund \$383,467 (Federal share) to the Federal Government for expenditures for compound drug ingredients that were not eligible for Medicaid coverage;
- work with CMS to resolve \$1,341,413 (Federal share) in expenditures for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and
- ensure that claimed Medicaid compound drug expenditures comply with Federal requirements, specifically:
  - claim expenditures only for compound drug ingredients that are dispensed before the termination dates listed on the quarterly drug tapes and
  - verify whether compound drug ingredients not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

## **STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In its comments on our draft report (included in their entirety as the Appendix), the State agency did not specifically agree with our refund in the first recommendation. However, the State agency commented that it would request that providers resubmit claims using correct drug codes or would recoup the amounts paid for terminated ingredients. The State agency said that it would adjust the Federal share to reflect these actions. The State agency agreed with our second recommendation to work with CMS to resolve the Federal share for drugs not listed on the quarterly drug tapes.

The State agency did not specifically agree with our third recommendation. The State agency commented that it would (1) continue to make changes to its claim processing system to ensure that terminated drugs are not reimbursed and (2) work with the new fiscal intermediary to change the reporting process in the new claims processing system to ensure that nondrug items are claimed in the appropriate reporting categories. The State agency did not address the last part of our third recommendation.

We continue to recommend that the State agency notify CMS when drugs are missing from the quarterly drug tapes.



## TABLE OF CONTENTS

	<u>Page</u>
<b>INTRODUCTION.....</b>	<b>1</b>
<b>BACKGROUND .....</b>	<b>1</b>
Medicaid Program.....	1
Medicaid Outpatient Prescription Drug Program .....	1
Compound Drugs .....	2
Reimbursement of Medicaid Expenditures.....	2
Prior Office of Inspector General Report.....	2
<b>OBJECTIVE, SCOPE, AND METHDOLOGY .....</b>	<b>2</b>
Objective .....	2
Scope .....	2
Methodology .....	3
<b>FINDINGS AND RECOMMENDATIONS .....</b>	<b>4</b>
CLAIMS FOR TERMINATED COMPOUND DRUG INGREDIENTS .....	4
CLAIMS FOR COMPOUND DRUG INGREDIENTS NOT LISTED ON QUARTERLY DRUG TAPES.....	5
RECOMMENDATIONS.....	6
STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE.....	6
<b>APPENDIX</b>	
DEPARTMENT OF HEALTH CARE SERVICES COMMENTS	

## **INTRODUCTION**

### **BACKGROUND**

#### **Medicaid Program**

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In California, the Department of Health Care Services (the State agency) administers the Medicaid program.

State Medicaid programs must provide certain medical services, including inpatient and outpatient hospital, physician, and family planning services. States also may offer certain optional services, such as outpatient prescription drugs, as long as the services are included in their approved State plans.

#### **Medicaid Outpatient Prescription Drug Program**

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including California, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.<sup>1</sup> The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The rebate agreements and related regulations (42 CFR § 447.510) require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on a quarterly Medicaid drug tape, makes adjustments for any errors, and sends the tape to the States. The tape indicates a drug's termination date,<sup>2</sup> if applicable, specifies whether the drug is less than effective,<sup>3</sup> and includes information that the States use to claim rebates from drug manufacturers. Drugs are identified on the tape by a unique 11-digit numerical code (drug code) that indicates the manufacturer, product, and package size. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement and to calculate the rebates that the manufacturers owe.

---

<sup>1</sup> The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program effective January 1, 1991. The program is set forth in section 1927 of the Act. Arizona is the only State that does not participate in the program.

<sup>2</sup> The termination date, which the manufacturer submits to CMS, reflects the shelf-life expiration date of the last batch sold for a particular drug code. However, if the drug is pulled from the market for health or safety reasons, the termination date is the date that the drug is removed from the market.

<sup>3</sup> The Food and Drug Administration determines whether drugs are less than effective. Such drugs lack substantial evidence of effectiveness for all conditions of use prescribed, recommended, or suggested in their labeling.

## **Compound Drugs**

Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form.<sup>4</sup> For each compound drug claim, CMS guidance states that the drug code and corresponding quantity for each ingredient must be included on the claim for Medicaid reimbursement.<sup>5</sup>

## **Reimbursement of Medicaid Expenditures**

In California, the State agency claims Medicaid expenditures on Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program. CMS reimburses the State agency based on the Federal medical assistance percentage (reimbursement rate) for the majority of claimed Medicaid expenditures, including some outpatient drug expenditures.

For Federal fiscal years (FY) 2004 and 2005, California's reimbursement rate for Medicaid expenditures varied from 50 percent to 90 percent.

## **Prior Office of Inspector General Report**

In April 2009, we issued a report on California's Medicaid outpatient drug expenditures for FYs 2004 and 2005.<sup>6</sup> We found that the State agency's claims for Federal reimbursement for these expenditures did not fully comply with Federal requirements. We excluded from our review approximately \$75 million for compound drug expenditures for which the State agency did not have readily available supporting documentation that identified the individual drug ingredients.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid compound drug expenditures complied with Federal requirements related to whether the compound drug ingredients were terminated, included on the CMS quarterly drug tapes, or less than effective.

### **Scope**

We reviewed approximately \$58.3 million (\$29.5 million Federal share) of the total \$75 million in Medicaid outpatient compound drug expenditures that the State agency claimed for FYs 2004

---

<sup>4</sup> The U.S. Pharmacopeia provides that "compounding involves the preparation and mixing of one or more components according to a written prescription specifically for individual patients." U.S. Pharmacopeia, *Compounding Background* (September 2008).

<sup>5</sup> The CMS guidance was published in 72 Fed. Reg. 39217, 39220 (July 17, 2007) in response to a commenter's question about billing of compound drugs.

<sup>6</sup> *Review of Medicaid Outpatient Drug Expenditures in California for Fiscal Years 2004 and 2005* (A-09-07-00039), issued April 27, 2009.

and 2005. The remainder of \$16.7 million consisted of \$1.2 million in claims for compound drug expenditures that the State agency voided and \$15.5 million in claims for compound drug expenditures for which the State agency did not provide ingredient detail because the information was not recorded in electronic format in the Rebate Accounting Information System. We will review the \$15.5 million in a separate audit.

We limited our internal control review to the State agency's procedures for determining whether compound drugs were eligible for Medicaid coverage and were accurately claimed for Federal reimbursement. We did not review the accuracy or completeness of the quarterly Medicaid drug tapes.

We performed our audit from May 2008 to March 2009 and conducted fieldwork at the State agency's offices in Sacramento, California.

### **Methodology**

To accomplish our objective, we reviewed applicable Federal laws, regulations, and program guidance and the State plan. We interviewed State agency officials responsible for identifying and monitoring drug expenditures and rebate amounts. We also interviewed staff responsible for reporting drug expenditures to CMS.

The State agency provided a detailed list of outpatient compound drug claims by quarter, which included the following: (1) claim number, (2) total claim reimbursement,<sup>7</sup> (3) date of service, (4) fees paid, (5) ingredients dispensed, (6) quantities dispensed, and (7) ingredient reimbursement amounts (ingredient costs). To determine which claims received Federal reimbursement, we compared the detailed list of compound drugs with the compound drugs excluded from our prior review.

We compared the compound drug ingredients with drug codes included on the CMS quarterly drug tapes for the period October 1, 1999, through June 30, 2006. We determined whether the compound drug ingredients for which the State agency claimed reimbursement were dispensed after the termination or less-than-effective dates listed on the quarterly drug tape. To account for reasonable delays in processing data for terminated drugs, we used the first day of the quarter after the State agency received the tape as the termination date if the termination dates were provided to the State agency retroactively. In addition, we determined whether the compound drug ingredients claimed for reimbursement were listed on the applicable quarterly drug tape.

We calculated the total questioned expenditures for terminated ingredients and set-aside expenditures for ingredients not listed on the quarterly tapes based on the ingredient costs. In determining questioned and set-aside amounts, we excluded ingredients for which we could not determine the precise amounts reimbursed to providers for these ingredients because (1) a beneficiary share-of-cost payment was associated with the claim or (2) the State agency

---

<sup>7</sup> For compound drugs, the State agency reimbursed providers the lesser of (1) total ingredient costs and fees or (2) the total amount billed by the provider. The State agency determined an ingredient's cost as the lesser of (1) the maximum payment that the State would make for that ingredient based on its quantity or (2) the amount that the provider billed for that ingredient.

reimbursed the provider based on the total billed. (For some of these claims, the ingredient costs exceeded the amount billed by the provider.)

We calculated the Federal share for questioned terminated drugs and the set-aside expenditures for drugs not listed on the quarterly drug tapes using the lowest reimbursement rate applicable for each quarter. We did not reduce the questioned drug expenditures by any rebate credits that the State agency received.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## **FINDINGS AND RECOMMENDATIONS**

The State agency's claims for reimbursement of Medicaid compound drug expenditures for FYs 2004 and 2005 did not fully comply with Federal requirements. Of the \$58.3 million (\$29.5 million Federal share) reviewed:

- \$759,078 (\$383,467 Federal share) represented expenditures for compound drug ingredients that were not eligible for Medicaid coverage because they were terminated drugs for which the termination dates were listed on the CMS quarterly drug tapes before the drugs were dispensed and
- \$2,649,556 (\$1,341,413 Federal share) represented expenditures for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Federal reimbursement.

The remainder of the \$58.3 million reviewed met the Federal requirements described in our objective.

The State agency had inadequate controls to ensure that all of its compound drug expenditures complied with Federal requirements related to whether the drug ingredients were terminated and included on the quarterly drug tapes.

## **CLAIMS FOR TERMINATED COMPOUND DRUG INGREDIENTS**

States are prohibited from claiming expenditures for drugs dispensed after the termination date. Pursuant to 21 CFR § 211.137, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf life for the product. The termination date equals the expiration date of the last batch sold, except in cases when the product is pulled from the market. In those cases, the termination date may be earlier than the expiration date.

According to the CMS Medicaid drug rebate program release to State Medicaid directors, number 19, the States “**MUST ... ASSURE** that claims submitted by pharmacists are **NOT** for drugs dispensed **AFTER** the termination date. These should be rejected as invalid since these drugs cannot be dispensed after this date.” (Emphasis in original.)

The CMS Medicaid drug rebate program release to State Medicaid directors, number 130, states that “... the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program.” The quarterly drug tapes list the Medicaid-covered drugs’ termination dates as reported by the drug manufacturers.

For FYs 2004 and 2005, the State agency claimed \$759,078 (\$383,467 Federal share) in expenditures for compound drug ingredients that, according to the State agency’s records, were dispensed after the termination dates shown on the quarterly drug tapes. For example, the State agency paid for the drug Prograf (an ingredient in a compound drug), which was dispensed on March 1, 2005; however, the drug’s termination date was December 31, 2003. The termination date appeared on the quarterly tapes from the quarter beginning April 1, 2002, through the quarter ending March 31, 2005. (Two other ingredients in this compound drug were listed on the quarterly tapes and did not have termination dates.) The claimed expenditure for the terminated drug ingredient was unallowable because it occurred after the drug’s termination date, which was listed on the quarterly tape when the State agency paid for the compound drug.

The State agency indicated that the CMS quarterly drug tapes do not provide timely information on drug termination dates. The State agency commented that it “often receives notification from a drug manufacturer years after the drug has been removed from the market and is obsolete, yet there is nothing on the CMS [quarterly drug tape] denoting any change in the drug status.” The State agency also indicated that its electronic formulary file allowed payments for some terminated drugs. Further, the State agency indicated that this file lists both Medicaid-covered and non-Medicaid-covered drugs and is used to process all pharmacy claims.

### **CLAIMS FOR COMPOUND DRUG INGREDIENTS NOT LISTED ON QUARTERLY DRUG TAPES**

Section 1927(a)(1) of the Act generally conditions Medicaid reimbursement for covered outpatient drugs on a requirement that manufacturers of those products enter into rebate agreements with CMS under which they pay rebates to the States.<sup>8</sup> The rebate agreements require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on the quarterly drug tapes and makes adjustments for any errors. According to the CMS Medicaid drug rebate program release to State Medicaid directors, number 130: “... the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program. ... If [a drug code] that is not on the last CMS [quarterly drug tape] you received is billed to you by a pharmacy ... check with CMS to assure that the [drug code] is valid ....” Furthermore, the CMS Medicaid drug rebate program release to State

---

<sup>8</sup> Pursuant to section 1927(a)(3) of the Act, a State may exempt certain drugs from the requirement to be covered by a drug rebate agreement if the State has determined that availability of the drug is essential to the health of Medicaid beneficiaries.

Medicaid directors, number 44, provides that: "... States must check the [quarterly drug tape] to ensure the continued presence of a drug product ...."

The CMS *Medicaid Drug Rebate Operational Training Guide*, page S13, states: "If you have paid for [a drug code] that is NOT on [the quarterly drug tape] you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid [drug code], you may have to ... recoup your funds."

For FYs 2004 and 2005, the State agency claimed \$2,649,556 (\$1,341,413 Federal share) in expenditures for compound drug ingredients that were not listed on the quarterly drug tapes. We set aside these potentially unallowable expenditures because the State agency did not verify with CMS whether drugs not listed on the quarterly tape were eligible for Medicaid coverage. According to State agency documentation, the claims processing system did not identify which drugs in the formulary file were eligible for Federal reimbursement. In addition, the State agency did not contact CMS to ensure that drugs not listed on the quarterly drug tapes were eligible for Medicaid coverage under the Act.

## **RECOMMENDATIONS**

We recommend that the State agency:

- refund \$383,467 (Federal share) to the Federal Government for expenditures for compound drug ingredients that were not eligible for Medicaid coverage;
- work with CMS to resolve \$1,341,413 (Federal share) in expenditures for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage; and
- ensure that claimed Medicaid compound drug expenditures comply with Federal requirements, specifically:
  - claim expenditures only for compound drug ingredients that are dispensed before the termination dates listed on the quarterly drug tapes and
  - verify whether compound drug ingredients not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

## **STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In its comments on our draft report (included in their entirety as the Appendix), the State agency did not specifically agree with our refund in the first recommendation. However, the State agency commented that it would request that providers resubmit claims using correct drug codes or would recoup the amounts paid for terminated ingredients. The State agency said that it would adjust the Federal share to reflect these actions. The State agency agreed with our second

recommendation to work with CMS to resolve the Federal share for drugs not listed on the quarterly drug tapes.

The State agency did not specifically agree with our third recommendation. The State agency commented that it would (1) continue to make changes to its claim processing system to ensure that terminated drugs are not reimbursed and (2) work with the new fiscal intermediary to change the reporting process in the new claims processing system to ensure that nondrug items are claimed in the appropriate reporting categories. The State agency did not address the last part of our third recommendation.

We continue to recommend that the State agency notify CMS when drugs are missing from the quarterly drug tapes.



# **APPENDIX**

**APPENDIX: DEPARTMENT OF HEALTH CARE SERVICES COMMENTS**



DAVID MAXWELL-JOLLY  
Director

State of California—Health and Human Services Agency  
Department of Health Care Services



ARNOLD SCHWARZENEGGER  
Governor

JAN 27 2010

Ms. Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
Office of Audit Services  
Office of Inspector General  
90 – 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

Dear Ms. Ahlstrand:

The California Department of Health Care Services (DHCS) has prepared its response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG), draft report entitled "Review of Medicaid Compound Drug Expenditures in California for Fiscal Years 2004 and 2005" (A-09-08-00034). DHCS appreciates the work performed by the OIG and the opportunity to respond to the draft report.

Please contact Ms. Traci Walter, Audit Coordinator, at (916) 650-0298 if you have any questions.

Sincerely,

Toby Douglas  
Chief Deputy Director  
Health Care Programs

cc: See next page

Ms. Lori A. Ahlstrand  
Page 2

**JAN 27 2010**

cc: Ms. Vanessa Baird  
Deputy Director  
Health Care Policy  
1501 Capitol Avenue, MS 4000  
P.O. Box 997413  
Sacramento, CA 95899-7413

Ms. Pilar Williams, Chief  
Pharmacy Benefits Division  
1501 Capitol Avenue, MS 4604  
P.O. Box 997413  
Sacramento, CA 95899-7413

Ms. Maria Enriquez, Chief  
Fiscal Intermediary and Contracts Oversight Division  
1501 Capitol Avenue, MS 4700  
P.O. Box 997413  
Sacramento, CA 95899-7413

**Department of Health Care Services**  
**Response to the Office of Inspector General's Draft Report Entitled**  
***Review of Medicaid Compound Drug Expenditures in California***  
***for Fiscal Years 2004 and 2005***  
**A-09-08-00034**

**Recommendation:** Refund \$383,467 (Federal share) to the Federal Government for expenditures for compound drug ingredients that were not eligible for Medicaid coverage.

**Response:** The Department will contact the providers who submitted the claims in which National Drug Code (NDC) numbers for terminated drugs were listed. The Department will ask the provider to resubmit the claim using the correct NDC number of the drug used or will recoup the amount paid for the terminated NDC from the provider. The Department will then adjust the Federal share to reflect these actions.

**Recommendation:** Work with the Centers for Medicare & Medicaid Services (CMS) to resolve \$1,341,413 (Federal share) in expenditures for compound drug ingredients that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid coverage.

**Response:** The Department will work with CMS to resolve this issue. In reviewing the spreadsheet provided by the Office of Inspector General (OIG), the Department has noted Food and Drug Administration (FDA) approved drugs that should have been on the quarterly CMS tape. The information on the CMS quarterly tape comes from manufacturers; the information submitted by manufacturers is not audited for completeness and therefore could be missing NDC numbers. Further investigation is required to assess why a particular NDC was not on the CMS quarterly tapes.

The Department also noted items that are non-drug items that should have been reported under other categories of the CMS-64 report (e.g. medical supplies). These items are eligible for federal matching funds.

**Recommendation:** Ensure that claimed Medicaid compound drug expenditures comply with Federal requirements, specifically:

- claim expenditures only for compound drug ingredients that are dispensed before the termination dates listed on the quarterly drug tapes and

- verify whether compound drug ingredients not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

**Response:**

As noted in response to previous OIG audits, the Department continues to make changes to the pharmacy claims processing system to ensure that terminated NDC numbers are not reimbursed. Because a compound drug claim can contain multiple ingredients, further analysis is required to determine how non-drug items that appear in a compound drug claim can be claimed on the CMS-64 appropriately. Because a new Medicaid Management Information System (MMIS) and change in the Fiscal Intermediary (FI) is imminent, the Department will work with the new FI to analyze and then change the CMS-64 reporting process in the new MMIS to ensure non-drug items are claimed in the appropriate reporting categories.